REMARKS/ARGUMENTS

In the Claims:

Claims 1-39, 46-49, 65-69 and 80-82 remain pending in the present application.

Generally

Based on the Examiner's assertion of the Clynch reference, and the specific sections of Clynch cited by the Examiner, Applicants respectfully submit that there appears to be a fundamental misunderstanding of the present invention, and of the Clynch invention. First, a distinction must be drawn between a prosthetic or orthotic, etc., *component* ("medical device" of Clynch) and a prosthesis or orthosis ("medical device" of the present invention). A prosthesis (e.g., a prosthetic leg), for example, might include components such as a socket, a liner, a suspension means, knee componentry, a pylon or other shin member, an ankle joint, and a foot (the presence of other components is also possible). When attempting to assemble such a prosthesis, a prosthetist is typically faced with selecting from a multitude of possible products in each component category (e.g., 20 different sockets, 30 different pylons, 10 different ankles, etc.). This can be the case not only because of the existence of more than one manufacturer for such components, but also because each manufacturer typically offers more than one model of each such component.

As such, it can be easily understood that the number of possible prostheses that can be assembled from various combinations of such components may be daunting to say the least. This is the problem that the present invention is designed to overcome. That is, based on one or a few criteria, the system and method of the present invention can sort through one or more databases containing the multitudes of components available with respect to a particular prosthesis type (e.g., leg, arm) and provide one or a number of acceptable prosthesis configurations using various combinations of qualifying components. Such criteria may include, for example, a prosthesis of the lowest cost, or of the lightest weight.

Clynch does not teach or suggest such an invention. Rather, Clynch is directed specifically and only to producing a custom prosthetic socket or other similar *interface component*, not to configuring, producing or assembling an entire prosthesis or orthosis. Specifically, Clynch teaches an improved system and method for producing a customized interface (e.g., socket) for a prosthetic or orthotic device by:

> casting the surface of a body portion;
>
> inspecting and marking critical areas of the body portion;
>
> causing the casting material to harden;
>
> removing the casting (model) from the body portion;
>
> scanning the body portion to produce a digitized image thereof;
>
> shrinking the digitized image to compensate for the thickness of the

casting (model);

manipulating (e.g., building up or relieving) areas on the digitized image to conform to critical areas of the body portion; and

producing code from the digitized image capable of controlling a mold making machine to make a mold of the cast body part, including any areas of build-up or relief.

The mold is then used to produce an interface component for the patient.

(See Clynch col. 2, ll. 28-48; col. 2, line 58 - col. 3, line 26; claim 1; Figure 1)

Clynch does not, however, teach or suggest a new method for designing, configuring or assembling the remainder of a prosthesis (of which the Clynch interface is merely a part). Rather, the remainder of the prosthesis or orthosis must still be configured by the known manual method that the present invention is specifically designed to render obsolete. That is, once a prosthetist, orthotist or other practitioner uses the system and method of Clynch to obtain a customized prosthetic or orthotic interface, the prosthetist/orthotist must still manually select the remainder of the components required to assemble the overall prosthesis, orthosis, etc.

Thus, for example, if a patient desires the lightest prosthetic leg possible, a prosthetist according to Clynch would still have to manually look up and consider the weight of what may be hundreds of prosthetic knee joints, ankle joints, pylons and other related leg components. The prosthetist must also consider whether each of the components of interest are compatible with other

such components of interest. Consequently, in order to arrive at the best possible prosthetic leg configuration(s), the prosthetist will have had to wade through potentially enormous numbers of possible component combinations.

On the other hand, the present invention allows a prosthetist or orthotist to easily and automatically configure one or more prostheses/orthoses based on patient preference or needs (a patient attribute), instead of having to undertake the arduous manual process described above. This is simply not the subject matter of Clynch, as is discussed in more detail below with regard to the Examiner's individual rejections.

Rejection of Claims 31-37, 39, 46-48, 65-67 and 82 Under 35 U.S.C. § 102(e)

The Examiner rejected claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e) as being anticipated by Clynch (US 6,463,351). As Applicants do not believe Clynch to teach the subject matter of the rejected claims, the rejection is respectfully traversed.

- With respect to independent claim 31 of the present application, the Examiner asserts that the claimed subject matter

> *querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient*

is taught by Clynch at col. 7, ll. 22-44 and 61-65, as well as col. 4, ll. 14-39 thereof. Applicant respectfully disagrees. Clynch at column 4 merely describes

that prosthetists, orthopedic surgeons, podiatrists, radiologists and plastic surgeons may practice *the invention* in creating prosthetic devices, orthotic devices, etc. This is no doubt true - but the *invention* of Clynch is the creation of a custom medical device *interface*, not an overall prosthesis. Thus, in order to configure the remainder of the medical device, these practitioners are currently forced to employ the manual system that the present invention renders obsolete. Further, Applicants respectfully request that the Examiner point out where in the cited portion of column 4 there appears any reference to a subset of medical device components, a digital repository, or the querying of a digital repository.

Similarly, there is absolutely no mention of a subset of medical device components, a digital repository of medical device components, or querying a digital repository for a subset of medical device components in column 7, ll. 22-44 or 61-65 of Clynch. By referring to line 14 of column 7, it is clear that the language cited by the Examiner describes only the digital image manipulation portion of the Clynch invention. (See also Fig. 3, referred to therein). Everything described in these sections of Clynch, and shown in Fig. 3, is related to a practitioner manipulating the digital image of the cast body part to produce areas of relief or build-up in the subsequently manufactured interface component. (See col. 1, ll. 33-38 for more general description). The referenced shrink and smooth operations, as well as the database storage of default modifications (i.e., pre-defined image changes), are all functions of image manipulation. Even the language of lines 47-52 refers to modifications that may be made to the *digital*

image in order to produce specific modifications to the finished interface component in the stated areas - *not* to medical device components. There is no discussion of a digital repository of medical device components, because Clynch is not concerned with anything more than a single component at a time. Further, the database referred to by the Examiner stores only information on previous changes made to similar digital body part (model) images, not information on medical devices.

* With respect to independent claim 46 of the present application, the Examiner makes the same assertions discussed above with respect to claim 31, and further asserts that the claimed subject matter

> *means for populating a digital repository with information corresponding to a plurality of individual medical device components*

is taught by Clynch at col. 4, ll. 14-39 and 49-53; and col. 7, ll. 61-63 thereof. Applicants have already addressed the lack of any such disclosure at col. 4, ll. 14-39 and col. 7, ll. 61-63 of Clynch. Col. 4, ll. 49-53 is similarly lacking in such teachings. Rather, this section of Clynch discloses only that a scan facility may be equipped with equipment that allows for the capturing (via scanning) of a 3-dimensional image of a target (body part) surface, and for conversion of the scanned data into a 3-dimensional image (see Fig. 3) that may be displayed on a computer. Once again, the cited sections of Clynch appear to be wholly devoid of any reference to a digital repository or to medical device components.

- The Examiner makes the same assertions with respect to independent claim 65 as were made with respect to claim 46. As Applicants have already discussed the deficiencies of these cited sections above, there is no need to repeat the arguments here.

As can be understood from the foregoing, Applicants have identified clear and material differences between Clynch and the subject matter of the rejected claims. Consequently, Applicants respectfully submit that Clynch cannot support a rejection of claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e).

Rejection of Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 35 U.S.C. § 103(a)

The Examiner rejected claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. (US 6,581,204). As Applicants do not believe Clynch in view of DeBusk et al. to teach the subject matter of the rejected claims, the rejection is respectfully traversed.

- With respect to independent claim 1 of the present application, the Examiner asserts that the claimed subject matter

> *a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component*

is taught by Clynch at col. 4, ll. 14-39 and lines 49-53 as well as col. 7, line 61 to col. 8, line 10 thereof, and that the claimed subject matter

a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient

is taught by Clynch at col. 7, ll. 22-44 and 61-65. Applicant again respectfully disagrees. Clynch at column 4, ll. 14-39 and lines 49-53 has been previously addressed. Clynch at col. 7, line 61 to col. 8, line 10, merely expounds slightly on the digital image manipulation discussion described by Applicants above. The digital image manipulation of Clynch is in no way related to the sorting and selection of multiple medical device components contemplated by the present invention. The cited sections of Clynch, like the remainder of said reference, are simply devoid of such teaching or suggestion, and the Examiner does not appear to have cited Debusk in the rejection of claim 1.

Applicants have again identified clear and material differences between Clynch and the subject matter of the rejected claims. Consequently, Applicant respectfully submits that Clynch cannot support a rejection of claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a).

Response to Arguments

Applicants reiterate the foregoing comments with respect to paragraphs 11-21 of the present office action. Applicants assert that most of the Examiner's

rejections of Applicants previous arguments appearing in paragraphs 11-21 have been addressed above. However, Applicants would like to specifically point out that:

- in paragraph 11, the body portions referred to by the Examiner are human body portions that may be scanned and imaged according to the invention of Clynch. They are *not* medical devices *nor* medical device components and, thus, their relevance is not apparent to Applicants;

- in paragraph 12, the patellar tenon bar, head of fibula and posterior wall extension referred to by the Examiner as "medical components" and appearing in col. 7, ll. 44-52 of Clynch, are in actuality various anatomical features of an amputated lower leg. These are human body part features, *not* "medical components";

- in paragraph 13, the tubular modeling material referred to by the Examiner is not a medical device or a medical device component. Rather, the modeling material is a casting material that is temporarily placed on a patient's body part to produce the 3-dimensional model that is eventually scanned, digitized and manipulated. As the modeling material does not remain on the patient's body, nor become part of the resulting interface component, there would be no reason for the practitioner or anyone else to ask the patient whether the tubular modeling material is comfortable or suits the patient's lifestyle;

- in paragraph 14, the scan data file referred to by the Examiner is not a stored patient attribute (weight, height, activity level, prosthesis weight

preference, etc.). Rather, the file the Examiner refers to is simply a saved digital image of the cast model, either before or after manipulation by a practitioner;

- in paragraph 15, Applicants reassert the same argument: operating a CAD software package to manipulate a 3-dimensional image of a body part (i.e., to produce areas of build-up or relief in the finished interface component) is clearly not the same as querying a database of medical device components in relation to selecting acceptable components for the construction of a prosthesis. Shape/size manipulation of a 3-dimensional image is simply not the same as, or even related to, sorting and selectively choosing components from a database of components based on predetermined criteria;

- in paragraph 16, Applicants again stress that this section of Clynch teaches only that an *interface component* created according to the described *invention* may be subsequently used in the assembly of, e.g., a prosthesis or orthosis. However, it is not taught or suggested that the invention can be used to create an overall prosthesis or orthosis. Rather, the manual configuration technique that the present invention seeks to render obsolete would currently need to be practiced in order to create a complete prosthesis or orthosis. Further, the invention of Clynch is directed *only* to the interface component of such a device. As the remainder of such a device does not contact the patient, it should be obvious that the invention of Clynch would not be applicable to other components; and

- in paragraph 21, the pull down menu options referred to by the Examiner are nothing more than menus that allow for a practitioner to perform particular manipulations of the 3-dimensional digital image of the modeled body part (much like the pull down menus of any CAD software package allow for the specific manipulation of a drawing model). Contrary to the Examiner's belief, these menus nor the software associated therewith, have anything whatsoever to do with selecting a subset of medical device components from a digital repository thereof.

For these reasons, and in light of the preceding arguments, Applicants respectfully submit that there is a misunderstanding of the present invention and of the invention described in Clynch. As such, Applicants respectfully request that the Examiner reconsider and reverse the pending rejections during further prosecution of the present application. At the very least, Applicants respectfully request that in light of the significant differences between the present invention and Clynch that have been identified herein, the Examiner revoke the final status of the present office action.

CONCLUSION

Applicants have distinguished the subject matter of the present invention over the teachings of the references cited as prior art by the Examiner. Therefore, Applicants respectfully submit that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. If, however, the Examiner

maintains the rejections, entry of the present amendment is respectfully requested as reducing the number of issues and placing this application in better condition for appeal.

Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

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